- Adverse effects
- Prescribing within clinical trials and availability of unlicensed medicines
- License extension

Conclusion: This investigation found variation between actual uptake of new medicines and the predictions provided in Forward Look reports and SMC advice. The 7 factors identified assist in explaining the variations observed, are useful in understanding the challenges in making accurate predictions, and provide some areas in which action could be taken to further develop and potentially improve predictions in Forward Look reports and SMC advice.

Disclosure of Interest: None declared.

OC011—PATENTED DRUG EXTENSION STRATEGIES ON HEALTH CARE SPENDING: A COST-EVALUATION ANALYSIS

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Introduction: Drug manufacturers developed "evergreening strategies" to compete with generic medication after patent termination. These include marketing of slightly modified follow-on drugs. We identified 8 follow-on drugs available in the canton of Geneva during the study period: 3 drugs for which an isomer had been marketed (levocetirizine as follow-on drug of cetirizine; escitalopram/citalopram; esomeprazole/omeprazole); 1 active metabolite (desloratidine – loratidine); 2 combination formulations of the originally patented drug (alendronic acid alone – alendronic acid combined with colecalciferol; simvastatin alone – simvastatin with ezetimib); 1 slow-release formulation (zolpidem extended release); and 1 structural analogue (pregabaline – gabapentine). We aimed to estimate the financial impact of these drugs on overall health care costs.

Patients (or Materials) and Methods: The impact of evergreening strategies on health care spending was analyzed in the community database that includes >73% of the total of insured patients. Costs were analyzed under 3 scenarios, assuming a replacement with the corresponding generic when available of: (1) all brand drug prescriptions; (2) all follow-on; and (3) both follow-on and brand prescriptions. The "extra-cost" was assessed by the difference between the total cost based on the observed data and the total cost estimated in the 3 scenarios.

Results: Based on our scenario 1 (no brand) and 2 (no follow-on) of "extra-costs," the health care system could have saved over the entire study period €15.9 (95% CI, 15.5–16.2) million and €14.4 (95% CI, 14.1–14.7) million if brand or follow-on drug prescriptions, respectively, had replaced. This amounted to €30.3 (95% CI, 29.8–30.8) million over the entire study period if brand and follow-on drug prescriptions were replaced at their corresponding community generic selling price equivalents when available (scenario 3).

Conclusion: Evergreening strategies have been successful in maintaining market share in Geneva, offsetting competition by generics and cost-containment policies. Therefore, health care providers and policy makers should be aware of the impact of evergreening strategies.

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OC013—A SIMPLIFIED METHOD FOR BUSULFAN THERAPEUTIC DRUG MONITORING USING DRIED BLOOD SPOT SAMPLING IN PEDIATRIC PATIENT UNDERGOING STEM CELL TRANSPLANTATION

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Introduction: Intravenously administered Busulfan (Bu) in children undergoing hematopoietic stem cell transplantation (HSCT) exhibits therapeutic window phenomenon requiring therapeutic drug monitoring. The dosage of Bu is adjusted based on the first dose pharmacokinetic parameters. Existing methods for the analysis of Bu require long turnaround times with relatively large amounts of blood collection for plasma separation.

Objective: To evaluate the utility of dried blood sampling (DBS) and dried plasma sampling (DPS) using only 5 µL of whole blood or plasma for therapeutic monitoring of Bu levels.

Patients (or Materials) and Methods: Venous blood samples were collected from 2 children after the infusion of Bu at doses1, 2, 3, 5, and 9 (n = 34). Then, 5 µL each of whole blood and plasma were spotted onto Whatman 903 DBS cards and dried at room temperature for 30 minutes. The entire spots were cut and then analyzed by a validated LC-MS/MS method. Bu was also measured by established gas chromatography coupled to mass spectrometry (GC-MS) method using plasma (n = 13) to compare both the methods.

Results: A good correlation was observed between the levels measured by DBS and DPS (r_2 = 0.95; slope = 0.84). The Bu levels measured by DPS (r_2 = 0.92; slope = 0.95) and DBS (r_2 = 0.91; slope = 0. 80) were correlated with those measured by GC-MS method. The levels estimated by DBS were less than those obtained by DPS and GC-MS methods. The hematocrit (Hct) values of 2 children were in the range of 25.6% to 30.3%, indicating the direct influence of Hct on the measured Bu levels measured by DBS sampling. Therefore, these 2 sampling methods can be used interchangeably with due consideration of the Hct value when whole blood sample is used. The plasma levels can be obtained from DBS levels using the formula "Plasma levels (analyte) = DBS levels analyte/ (1 – hematocrit)." The plasma levels of Bu estimated using this formula were higher than